

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference INTM-029WO	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/07509	International filing date (day/month/year) 11 March 2004 (11.03.2004)	Priority date (day/month/year) 28 March 2003 (28.03.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/20, 45/00 and US Cl.: 424/85.5, 85.7			
Applicant INTERMUNE, INC.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u> </u> sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u> </u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 08 September 2004 (08.09.2004)		Date of completion of this report 06 December 2004 (06.12.2004)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Janet L. Andres <i>J. Roberts for</i> Telephone No. (571) 272-1600	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/07509

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-58 _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☒ the claims:

pages 59-61 _____ as originally filed/furnished
pages* NONE _____ as amended (together with any statement) under Article 19
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☐ the drawings:

pages NONE _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/07509**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>2-6, 10-28, 30</u>	YES
	Claims <u>1, 7-9, 29</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-30</u>	NO
Industrial Applicability (IA)	Claims <u>1-30</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:

Claims 1, 7-9, and 29 lack novelty under PCT Article 33(2) as being anticipated by U.S. patent 5,831,062. This patent teaches that alpha interferons, in particular consensus interferon, can be used to treat poxviruses in column 5, lines 46-51.

Claims 2-6 lack an inventive step under PCT Article 33(3) as being obvious over the '062 patent, cited above, in view of Moss, 1996. The '062 patent teaches as set forth above but fails to teach co-administration of vaccinia virus. Moss teaches on p. 11341 that vaccinia virus has been used to treat smallpox. It would be obvious to the artisan of ordinary skill to combine these two teachings to administer interferon alpha and vaccinia virus to treat smallpox. One of ordinary skill would be motivated to do so because both have been shown to be effective for this purpose.

Claims 10 and 16-18 lack an inventive step under PCT Article 33(3) as being obvious over Alcamí et al., 1996. Alcamí et al. teaches that interferon gamma is an important anti-viral agent whose action is inhibited by poxviruses. Alcamí et al. does not teach administration of exogenous interferon gamma; however, it would be obvious to the artisan of ordinary skill to administer interferon gamma, since Alcamí et al. teaches that it is an effective agent. The artisan of ordinary skill would expect the administration of extra interferon gamma to overcome the ability of the virus to inhibit its activity and allow it to function as an anti-viral agent.

Claims 11-15 lack an inventive step under PCT Article 33(3) as being obvious over Alcamí et al. in view of Moss. Each of these references teaches as set forth above. Neither teaches co-administration. It would be obvious to the artisan of ordinary skill to combine these two teachings to administer interferon gamma and vaccinia virus to treat smallpox. One of ordinary skill would be motivated to do so because each would be effective for this purpose and it is thus *prima facie* obvious to combine them.

Claims 19, 25-27, and 30 lack an inventive step under PCT Article 33(3) as being obvious over the '062 patent in view of Alcamí et al. Each of these references teaches as set forth above. Neither teaches co-administration. It would be obvious to the artisan of ordinary skill to combine these two teachings to administer interferon gamma and interferon alpha to treat smallpox. One of ordinary skill would be motivated to do so because each would be effective for this purpose and it is thus *prima facie* obvious to combine them.

Claims 20-24 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Moss. Each of these references teaches as set forth above but none teaches co-administration of all three agents. It would be obvious to the artisan of ordinary skill to combine these three teachings to administer interferon gamma and interferon alpha as well as vaccinia virus to treat smallpox. One of ordinary skill would be motivated to do so because each would be effective for this purpose and it is thus *prima facie* obvious to combine them.

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Supplemental Box

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of U.S. patent 6,177,074. The '062 patent, Moss, and Alcamì et al teach as set forth above but fail to teach co-administration of ribavirin. The '074 patent teaches in column 5, lines 14-37, that ribavirin is usefully co-administered with alpha interferon and further that the combination can be used to treat poxviruses. It would be obvious to the artisan of ordinary skill to combine these four teachings to administer interferon gamma and interferon alpha with ribavirin as well as vaccinia virus to treat smallpox. One of ordinary skill would be motivated to do so because each would be effective for this purpose and it is thus *prima facie* obvious to combine them.

Claims 1-30 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.